# An Open-Label Drug-Drug Interaction Study in Healthy Male Subjects to Explore the Effects of Single and Multiple Doses of JNJ-39393406 on the Pharmacokinetics of a Single Oral Dose of Midazolam

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The purpose of this investigation is: • To examine the effect of single and multiple doses of the new drug JNJ-39393406 (the study medication) on absorption, metabolism and excretion by the body after single administration of the drug midazolam.• To...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Mental impairment disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON33240

**Source**
ToetsingOnline

**Brief title**
JNJ-39393406 ALZ1001 study

### Condition

- Mental impairment disorders
- Schizophrenia and other psychotic disorders

**Synonym**
alzheimer, psychose

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Janssen-Cilag
**Source(s) of monetary or material Support:** Janssen-Cilag International N.V.

## Intervention

**Keyword:** Drug-drug interaction, Healthy males, Open-label

## Outcome measures

### Primary outcome

The primary purpose of this investigation is to examine the effect of single

and multiple doses of the new drug JNJ-39393406 (the study medication) on

absorption, metabolism and excretion by the body after single administration of

the drug midazolam.

### Secondary outcome

The other purpose of this investigation is to examine the safety and

tolerability of the new drug JNJ-39393406 (the study medication).

# Study description

### Background summary

JNJ-39393406 is a new medication developed for the treatment of symptoms of decreased cognition in schizophrenia and Alzheimer disease.

### Study objective

The purpose of this investigation is:
• To examine the effect of single and multiple doses of the new drug JNJ-39393406 (the study medication) on absorption, metabolism and excretion by the body after single administration of the drug midazolam.
• To examine the safety and tolerability of the new drug JNJ-39393406 (the

study medication).

## Study design

This investigation is a open label drug-drug interaction study.

## Intervention

The study will start with a screening. A physical examination and different standard test (ECG, blood pressure) will be performed during the screening appointment. Blood and urine samples will be taken for laboratorium tests and an alcohol breath test and drug screen will be performed.

During the confinement the medication will be administered to the subjects on different occasions. Blood
samples will also be taken at several occasions. Adverse events will be registered. ECG and vitals will be judged.

At the end of the study a follow-up visit will take place.

## Study burden and risks

The trial medication JNJ-39393406 is not a registered drug. This drug has been given to volunteer before and was well tolerated. Side effects were mentioned which are probably due to the medication. These were dizziness, headache and feeling tired.

NJ-39393406 has been extensively tested on animals according to official guidelines. Comparison of the results in the animal studies of the clinical starting doses showed no undesired effects. At higher doses the following undesired effects were seen: rise of liver values, small changes of the clotting parameters, increase of the white blood cell values and increase of red blood cells. At highest doses there were indications of increased breaking up of red blood cells, accumulation of pigment in the liver and excessive iron deposits near the spleen after investigation of the tissue of the laboratory animals. The drug can also give a light irritation of the eyes and occasionally an effect was seen on coordination and grip. After a recovery period of 4 weeks following treatment of 4 weeks the animals recovered and no effects could be seen anymore.

Testing of the heart showed no undesired effects within the investigated dose ranges compared with the doses used for this study.

Midazolam (Dormicum®) is a registered drug belonging to the group of benzodiazepines. They work relaxing, give muscle relaxation and decrease feeling of fear. Physicians prescribe it for sleeplessness and for a short

period for anxiety . The most common side effects are drowsiness during the day, muscle weakness, feelings of confusion, tiredness and double vision. You will get midazolam in a low dose (2 mg) because the effect can be increased by the drug medication JNJ-39393406.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

### Inclusion criteria

Males
Between 18 and 55 years of age (inclusive)
BMI between 18 en 30 kg/m^2 (inclusive)

### Exclusion criteria

Clinical significant abnormalities for physical examination

## Study design

### Design

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| Study type: | Interventional |
| Intervention model: | Crossover |
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Prevention |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 24-07-2009 |
| Enrollment: | 12 |
| Type: | Actual |

### Medical products/devices used

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| Product type: | Medicine |
| Brand name: | Dormicum® |
| Generic name: | Midazolam |
| Registration: | Yes - NL intended use |

## Ethics review

Approved WMO

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| Date: | 15-07-2009 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |

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| Approved WMO Date: | 23-07-2009 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| EudraCT | EUCTR2009-013637-25-NL |
| CCMO | NL28935.056.09 |